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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/601,410

06/23/2003

Joseph P. Desmond

BSCU-039/00US

7691

22903

7590

11/25/2008

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/601,410	Applicant(s) DESMOND, JOSEPH P.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2003 2/24/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 5, 9 and 23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant claims "the inner diameter of the first hollow member is *less* than the outer diameter of the second hollow member", which is not supported by the specification of the drawings. Based on the drawings, the claim will be examined to read "the inner diameter of the first hollow member is *greater* than the outer diameter of the second hollow member", however appropriate correction is required in the response to this Office action.

3. **Claim 9** recites the limitation "longitudinal axis" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.
4. **Claim 23** recites the limitation "retaining slot" in line 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-5, 7, 8, 11, 12, 16-19, 22-25, 27-30, 32 and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by **Stouder (WO 98/36785)**.

Regarding claims 1, 2, 11, 12, 16-18, 29, 30 and 32, Stouder discloses a first hollow member (12), a second hollow member (30), which is a cylinder (Figure 1) and a length adjustment element (spacing members, 32 and 34) in communication with both a distal end of the first hollow member (12) and a proximal end of the second hollow member (30) wherein the length adjustment element (32 and 34) adjustably join together, coaxially the first hollow member and the second hollow member. When joined, the first and second hollow members have a selectable length longer than the longest of the first and second length, and the length adjustment members are threads with an interference fit and a slot defined by the opening in the distal end of the first hollow member (12) wherein the first thread is a female thread and the second thread is a male thread (page 9, lines 13-30).

Regarding claims 3 and 4, Stouder discloses at least one of the first hollow member and the second hollow member is comprised of a semi-rigid material (plastic; page 16, line 32).

Regarding claim 5, Stouder discloses the inner diameter of the first hollow member is greater than the outer diameter of the second hollow member (Figure 1, it can be seen that the diameter of the first hollow member is larger than the second hollow member, allowing the second hollow member to fit inside the first).

Regarding claim 7, Stouder discloses the distal end of the first hollow member includes a beveled edge (Figure 2, the distal end is tapered).

Regarding claim 8, Stouder discloses the distal end of the second hollow member defines an end face adapted to facilitate insertion into the body (page 10, lines 11-15).

Regarding claim 19, Stouder discloses an elastomeric member (o-ring, 40) disposed between the distal end of the first member and the proximal end of the second end (page 9, lines 31-35).

Regarding claims 22 and 23, Stouder discloses the device having a fastener (16) at the proximal end of the first hollow member with a retaining slot (20) to provide an interference fit for securing the guidewire device (page 8, lines 29-34).

Regarding claims 24 and 25, Stouder discloses a locking element comprising a wedge (136) between the proximal end of the second member and the adjustable element (page 15, line 33 to page 16, line 4).

Regarding claims 27, Stouder discloses a fluid tight seal (page 9, lines 32-35).

Regarding claims 28, Stouder discloses a washer (18) adapted for maintaining a fluid tight seal (page 8, lines 25-26).

Regarding claims 33, Stouder discloses a flange (20; Figure 1) for attaching medical instruments thereto.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 6 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stouder (WO 98/36785)**.

Regarding claim 6, Stouder discloses the invention substantially as claimed above, but does not disclose the medical instrument being a catheter. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

Regarding claim 26, Stouder discloses the invention substantially as claimed above, but fails to specifically disclose the locking device comprising a post and groove.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a post and groove locking member, as a post and groove is an obvious variation of a male and female thread locking adjustment member as disclosed in claim 11. In this case, the first thread acts as a "groove" with the second thread acting as a "post", and coupling to the first thread.

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10. **Claims 9 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stouder (WO 98/36785)** in view of **Hinchliffe (US 5,957,888)**.

Regarding claims 9 and 10, Stouder discloses the invention substantially as claimed above, but fails to disclose the end face residing in a plane defining an acute angle with the longitudinal axis and including a chamfered edge.

However, Hinchliffe teaches the end face of the second hollow member being chamfered (tapered), and creates an acute angle with the longitudinal axis of the device (Figure 4, distal end is tapered).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to taper the end face of the instrument to facilitate insertion into the body due to the more streamlined profile a tapered edge would create.

11. **Claims 13-15 and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stouder (WO 98/36785)** in view of **Peterson (US 2001/0029353)**.

Regarding claims 13-15 and 31, Stouder discloses the invention substantially as claimed above, but fails to disclose a notch and detent system as the length adjustment element.

However, Peterson teaches a notch (116b) and detent (112c) system to allow for expansion and contraction of the combined length of the medical device (paragraph 37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a notch and detent system to provide the medical device with a method of adjustability to allow the device to be used on a variety of patients, from infants to large adults (paragraphs 8 and 37).

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12. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stouder (WO 98/36785)** in view of **Arramon et al. (US 6,875,219)**.

Regarding claims 20 and 21, Stouder discloses the invention substantially as claimed above, but fails to disclose a radio opaque marking.

However, Arramon et al. teaches a radiopaque marker (104; column 9, lines 26-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a radiopaque marker to allow for the device to be visualized with an imaging device during a surgical procedure (column 9, lines 33-39).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731